

## **REMARKS**

Claims 1 through 17, 19 through 36 and 38 are pending in the application.

Claims 1 through 6, 10, 11, 13, 14, 19 through 23, 25, 26, 29 through 32 and 38 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,559,189 to Baker, Jr. et al. (Baker).

Baker is directed to compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses. Primarily, the Baker invention, as evidenced by the Examples and the claims, is oil-in-water emulsion compositions and methods for decontaminating a sample with such emulsion compositions.

Claim 1 recites a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition has at least one antibacterial agent and at least one finishing agent. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon having an absorbent material and a composition comprising at least one antibacterial agent and at least one finishing agent. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Applicants respectfully submit that Baker does not disclose each and every element of the claimed invention and therefore does not anticipate the claimed invention under §102(e). As noted above, Baker's primary focus is oil-in-water emulsion compositions and methods for decontaminating a sample with such emulsion compositions, as evidenced by their detailed description of the invention, examples and the claims.

Baker discloses the use of the oil-in-water emulsions in medical devices. Buried in a laundry list of possible medical devices is a tampon. The laundry list disclosure of a tampon is the only reference to a tampon in the entire Baker patent, which is over 80 pages long. The mere mention of an element of the claimed invention in a piece of prior art, buried in a long list of possible combinations of products and chemical solutions, does not describe the claimed invention with enough detail and clarity to disclose it to a person having ordinary skill in the art. Such a passing mention does not release the information to the public and thus can not anticipate the claimed invention under §102(e). See In re Wiggins, 179 U.S.P.Q. 421, 425 (C.C.P.A. 1973); In re Schoenwald, 22 U.S.P.Q.2d 1671, 1671 (Fed. Cir. 1992).

In the instant case, the mere mention of a tampon buried in a long list of other possible products that can be used with Baker's oil-in-water emulsion compositions clearly fails to disclose or suggest the claimed invention to one of ordinary skill in the art. Moreover, nowhere in Baker is there a disclosure or suggestion of the use of a tampon with at least one antibacterial agent and at least one finishing agent that synergistically neutralizes TSST-1 toxin and reduces *Staphylococcus aureus* bacteria growth, as claimed. Therefore, Baker does not anticipate the claimed invention.

Applicants further submit that the Office Action incorrectly concludes that Baker inherently discloses the treatment of TSST-1 toxin by the claimed invention. The fact that a certain result or characteristic may occur or be present in the prior art

is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

It is respectfully submitted that the Action clearly fails to cite any rationale or extrinsic evidence found in Baker, or anywhere else, that makes clear that Baker's composition possesses the synergistic TSST-1 toxin neutralization and *Staphylococcus aureus* antibacterial properties unexpectedly found with the presently claimed composition. Therefore, the Action impermissibly relies on a mere possibility that the claimed properties may possibly, but not admittedly, be capable in the cited prior art. Absent any extrinsic evidence making clear that the claimed properties are necessarily present in Baker, the Action cannot and does not establish inherency. It is only through the present application that a tampon with such a composition having synergistic neutralization and antibacterial properties is disclosed or suggested.

Therefore, for at least the reasons set forth above, Baker fails to anticipate claims 1 through 6, 10, 11, 13, 14, 19 through 23, 25, 26, 29 through 32 and 38. As such, Applicants respectfully request that reconsideration and withdrawal of the §102(e) rejection of these claims.

Claims 7 through 9, 24, 27 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker.

Dependent claim 7 depends indirectly from claim 1. Dependent claim 27 indirectly depends from claim 20. Both claims recite the feature that one or more quaternary ammonium compounds are present in an amount of about 1.0 wt.% based on the total weight of the tampon.

Dependent claim 8 depends indirectly from claim 1. Dependent claim 24 depends indirectly from claim 20. Both claims recite the feature that one or more quaternary ammonium compounds are present in an amount about 0.01 wt.% to about 5 wt.% based on the total weight of the tampon.

Dependent claim 9 depends directly from claim 1. Dependent claim 28 depends directly from claim 20. Both claims recite the feature that at least one antibacterial agent is present in an amount about 0.01 wt.% to about 5 wt.% based on the total weight of the tampon.

Applicants respectfully submit that, as noted above, Baker fails to disclose or suggest the claimed invention recited in at least independent claims 1 and 20. Therefore, it follows that Baker also fails to disclose or suggest the claimed invention recited in claims 7 through 9, 24, 27 and 28, as these claims depend either directly or indirectly from claims 1 and 20.

Further, Applicants respectfully submit that the claimed features recited in claims 7 through 9, 24, 27 and 28 are not disclosed or suggested in Baker. As conceded by the Action, Baker is silent as to the amount of antibacterial agent based on the total weight of a tampon. This deficiency in Baker is not surprising since Applicant's claimed invention is the result of unexpected results. Namely, antibacterial agent present in the claimed amounts in combination with at least one finishing agent yields a tampon with synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus*

bacteria growth. The claimed synergistic properties are clearly set forth in the data detailed on pages 12 and 13 of the present specification.

To the contrary, there is no disclosure or suggestion anywhere in Baker of the claimed tampon having the antibacterial agent present in such an amount in conjunction with at least one finishing agent that results in synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth. Therefore, the claimed invention is not rendered obvious by Baker.

In lieu of the above, Applicants respectfully submit that claims 7 through 9, 24, 27 and 28 are patentably distinguishable over Baker. As such, reconsideration and withdrawal of the §103(a) rejection of these claims is respectfully requested.

Claims 12, 17, 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker.

Dependent claim 12 depends indirectly from claim 1. Dependent claim 36 depends indirectly from claim 20. Both claims recite the feature that one or more surfactants are present in an amount about 0.01 wt.% to about 10 wt.% based on the total weight of the tampon.

Dependent claim 17 depends directly from claim 1. Dependent claim 35 depends directly from claim 20. Both claims recite the feature that at least one finishing agent is present in an amount about 0.01 wt.% to about 10 wt.% based on the total weight of the tampon.

Applicants respectfully reiterate that, as noted above, Baker fails to disclose or suggest the claimed invention recited in at least independent claims 1 and 20. Therefore, it follows that Baker also fails to disclose or suggest the claimed invention

recited in claims 12, 17, 35 and 36, as these claims depend either directly or indirectly from claims 1 and 20.

Further, Applicants respectfully submit that the claimed features recited in claims 12, 17, 35 and 36 are not disclosed or suggested in Baker. As conceded by the Action, Baker is silent as to the amount of finishing agent based on the total weight of a tampon. Again, similar to the argument set forth above with respect to the claimed antibacterial agent concentrations, this deficiency in Baker is not surprising since Applicant's claimed invention is the result of unexpected results. Namely, finishing agent present in the claimed amounts in combination with at least one antibacterial agent yields a tampon with synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth. The claimed synergistic properties are clearly set forth in the data detailed on pages 12 and 13 of the present specification.

To the contrary, there is no disclosure or suggestion anywhere in Baker of the claimed tampon having finishing agent present in such an amount in conjunction with at least one antibacterial agent that results in synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth. Therefore, the claimed invention is not rendered obvious by Baker.

In lieu of the above, Applicants respectfully submit that claims 12, 17, 35 and 36 are patentably distinguishable over Baker. As such, reconsideration and withdrawal of the §103(a) rejection of these claims is respectfully requested.

Claims 15, 16, 33 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker as applied to claims 14 and 32 above, and further in view of U.S. Patent No. 6,335,012 to Fischetti et al. (Fischetti).

Baker is summarized above. Fischetti is directed to a method for treating dental caries comprising administering a composition comprising an effective amount of at least one lytic enzyme produced by a bacteriophage specific for the bacteria.

Applicants respectfully reiterate that, as noted above, Baker fails to disclose or suggest the claimed invention recited in at least independent claims 1 and 20. Therefore, it follows that Baker also fails to disclose or suggest the claimed invention recited in claims 15, 16, 33 and 34, as these claims depend either directly or indirectly from claims 1 and 20. Fischetti fails to cure any of the deficiencies of Baker, since Fischetti fails to disclose or suggest a tampon, let alone a tampon with the claimed antibacterial agent and finishing agent with synergistic properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Moreover, Applicants respectfully submit that Fischetti is non-analogous art. In order for prior art to be used to defeat a claimed invention on obviousness grounds, the art must either be in the same field of endeavor, or “reasonably pertinent” to the particular problem the inventor is trying to solve. In re Clay, 23 U.S.P.Q.2d 1058, 1060 (Fed. Cir. 1992)(citations omitted)(holding that two pieces of art that both dealt with the petroleum industry were nonetheless non-analogous). The Baker and Fischetti references are not in the same field of endeavor, and therefore fail the first prong of the *Clay* test. Baker deals with emulsion-type antimicrobial compositions generally, and Fischetti deals with bacteria specifically in the mouth and teeth only.

Furthermore, the Fischetti reference is not reasonably pertinent to the problem being solved by the claimed invention. The claimed invention is concerned with a tampon that neutralizes the production of TSST-1 toxin and reduces *Staphylococcus aureus* bacteria growth in the vagina, whereas Fischetti is concerned with oral

infections. The Fischetti reference is therefore non-analogous to the claimed invention, and cannot be used to render the claimed invention obvious.

Therefore, claims 15, 16, 33 and 34 are patentably distinguishable over the cited art taken alone or in combination. Reconsideration and withdrawal of the §103(a) rejection of these claims is respectfully requested.

In view of the foregoing, Applicants respectfully submit that all claims presented in this application are patentably distinguishable over the cited prior art, taken alone or in combination. Accordingly, Applicants respectfully request favorable consideration and the passage of all claims to allowance.

August 13, 2004

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", is written over a horizontal line.

Charles N.J. Ruggiero

Attorney for Applicants

Reg. No. 28,468

Ohlandt, Greeley, Ruggiero & Perle, L.L.P.

One Landmark Square, 10<sup>th</sup> Floor

Stamford CT 06901-2682

Tel: 203-327-4500

Fax: 203-327-6401